REMARKS

Reconsideration of the Examiner's rejection of the present application is requested respectfully in view of the above amendments and the following remarks. In accordance with Rule 1.116, the amendments to the claims are to comply with requirements of form or to present the claims in better form for consideration on appeal.

TELEPHONIC INTERVIEWS

As an initial matter Applicants' undersigned attorney wishes to express his gratitude to the Examiner for the helpful telephonic interviews that were held on November 19, 2008, November 20, 2008, and June 1, 2009. The substance of the three telephonic interviews may be summarized as follows:

a. November 19, 2009:

The undersigned and the Examiner discussed the status of the pending claims and, more specifically, the reasons for non-entry of the claim amendments that were submitted with Applicants' reply of April 17, 2008. Although the Examiner noted in retrospect that the amendments appeared to have been consistent with the guidance provided in the Final Office Action dated December 21, 2007, (i.e., the amendment merely attempted to narrow the scope of the claims, highlighting two specific drug combinations that were already recited in the claims), the undersigned agreed that the scope of the amended claim(s) could have been more readily appreciated if the amendment had removed further extraneous text from the claim. The undersigned submits that the amendments submitted in the Instant Response have been drafted accordingly. The Examiner and the undersigned also discussed the examples provided in the specification and their relevance to certain aspects of the invention.

b. November 20, 2008

The Examiner and the undersigned focused on one aspect of the invention described in the Instant Application, treatment of subjects via administration of the inventive combination intravenously, and discussed various approaches to clearly capturing this aspect in the claims.

The Examiner and the undersigned agreed in principle on an approach however specific claim language was not finalized.

c. June 1, 2009

The undersigned and the Examiner again discussed the aspect of the invention discussed during the November 20, 2008, teleconference, this time in view of the very limited scope of the rejection provided the Instant Office Action and the data presented in the application. More particularly, the Examiner and the undersigned agreed to limit the claims to that aspect of the invention which relates to a pharmaceutical preparation for intravenous administration of a synergistic combination of the recited active components. With respect to the synergistically therapeutic amounts of the active agents, the undersigned and the Examiner further agreed to limit the claims to formulations which provide 2'-{[2-(4-methoxyphenyl)acetylamino]methyl} biphenyl-2-carboxylic acid (2 pyridin-3-ylethyl)amide at doses of about 0.3 mg/kg/h to about 3 mg/kg/h.

STATUS OF THE CLAIMS

Claims 1-12, as amended in Applicants' Amendment and Response filed April 17, 2008, were pending at the time of the Instant Office Action. Of these, claims 1-7 were presented for examination and claims 8-12 were withdrawn as being directed to non-elected subject matter. In the Instant Response claims 1-4 and 6-12 have been cancelled and claim 5 has been amended. No new matter has been added by these amendments. Accordingly, claim 5 is now presented for review.

CLAIM AMENDMENTS

Claims 1-4 and 6-12 are cancelled.

Claim 5 is amended in order to adopt an independent form, and to limit the scope of the claim to pharmaceutical preparations which (a) are amenable to intravenous administration of (b) a pharmaceutical preparation comprising the subject combination, (c) wherein the dose of the 2'-{[2-(4-methoxyphenyl)acetylamino]methyl} biphenyl-2-carboxylic acid (2 pyridin-3-ylethyl)amide is provided at about 0.3 mg/kg/h to about 3 mg/kg/h; i.e., the dose range at which the data in the instant application demonstrate not only a synergistic effect, but below which the

data indicate the stated compound may be able to provide a significant therapeutic effect on atrial fibrillation when administered as a sole agent. (See, e.g., the specification at Table 3.)

Applicants reserve the right to file one or more continuing application(s) directed to any subject matter cancelled hereby. In view of the above amendment and discussion, the Examiner is respectfully requested to reconsider and withdraw the present rejection under 35 U.S.C. §103(a).

SUMMARY OF OFFICE ACTION

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Brendel et al., (US Patent No. 6,531,495, hereinafter Brendel '495), in view of Smith et al. (US Patent Pub. No. 2002/0161018, hereinafter Smith). The rejection is respectfully traversed.

DISCUSSION

a. The rejection under 35 U.S.C. §103(a)

Although Claims 1-7 stand rejected under 35 U.S.C. §103(a), as explained in detail in Applicants' Amendment and Response to Office Action submitted April 17, 2008, (see discussion at pages 9-11 therein), and acknowledged by the Examiner in the Instant Office Action (see page 3, paragraph 5 therein), there is sufficient evidence provided in the specification itself to demonstrate unexpected synergism for the combination of Example 1 with, e.g., ibutilide and with dofetilide. The combination of the compound of Example 1, i.e., 2'-{[2-(4-methoxyphenyl)acetylamino]methyl}biphenyl-2-carboxylic acid (2-pyridin-3-ylethyl)amide, with ibutilide and with dofetilide were specifically set forth in the text of claim 5, which depended from claim 1. In view of the instant amendments the claims are now limited to these two particular combinations. Further, as agreed with the Examiner during the June 1, 2009, teleconference, the claims are now limited to (a) intravenous formulations (or the use thereof) containing (b) synergistic amounts of the component active ingredients which (c) deliver a clearly synergistic amount of 2'-{[2-(4-methoxyphenyl)acetylamino]methyl}biphenyl-2-carboxylic acid (2-pyridin-3-ylethyl)amide; i.e., from 0.3 mg/kg/hr to about 3 mg/kg/hr.

Accordingly, to the extent that the instant rejection is applied to any claims that are herein cancelled, such rejection has been rendered moot by the instant amendments. Further, to the extent that the instant rejection is applied to claim 5, Applicants respectfully submit that the

instant amendments have overcome the rejection, and that the claims is therefore in condition for allowance.

b. The question raised in the Instant Office Action at page 4, 3d paragraph.

In passing, Applicants note that the Examiner has questioned why in Table 3 the test subject receiving a 10mg/kg/hr dose of the Kv1.5 blocker, 2'-{[2-(4-methoxyphenyl)acetylamino]methyl}biphenyl-2-carboxylic acid (2-pyridin-3-ylethyl)amide, experienced cardioversion even before administration of the IKr blocker ibutilide, whereas the second test subject (Table 4; dofetilide) did not. In response Applicants respectfully remind the Examiner that the ability of the test Kv1.5 blocker to initiate cardioversion at high doses, even without concomitant administration of an IKr channel blocker, was expected. On the other hand, what was not expected, and what the invention provides, is the ability to initiate cardioversion *without* the need for high-dose administration of a Kv1.5 blocker.

It is submitted that the claims in the present application are now in condition for allowance, and action to that effect is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment resulting from this Amendment to Deposit Account 18-1982.

Respectfully submitted,

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